

K962442

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II. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

ESPE is submitting a 510(k) premarket notification for modifications to its 510(k) submissions for tooth shade resin material, tradenamed Pertac®-Hybrid® (K900510), and the corresponding bonding agent, tradenamed Pertac® Universal Bond (K904289). The modified materials, referred to by the tradenames Hytac® Aplitip® and Hytac® OSB, respectively, are intended as compomer filling material and corresponding bonding agent. Hytac® Aplitip® is a compomer filling material indicated for the following uses: (1) fillings in deciduous teeth; (2) fillings in Class V cavities; (3) eroded and abraded cervical areas; (4) fillings in Class III cavities; and (5) temporary fillings in Class I and II cavities. Hytac® OSB is a light cured bonding agent for use with compomer filling materials.

With respect to Hytac® Aplitip®, ESPE is claiming substantial equivalence to its previously cleared Pertac®-Hybrid® product and Ivoclar's Compoglass® (K951836). These products have similar intended uses and, in the case of Compoglass®, the same principal ingredient composition. To support substantial equivalence to predicate products, the physical and technical

characteristics, as well as the water soluble fluoride content, of Hytac® Aplitip® have been compared to those of Pertac®-Hybrid® and Ivoclar's Compoglass®. In addition, certain tests have been undertaken on the final Hytac® product, including cytotoxicity, Ames, skin irritation, eye irritation, acute oral toxicity and sensitization. Results of these studies indicate that the final product shows no adverse toxicity results.

With respect to Hytac® OSB, ESPE is claiming substantial equivalence to its previously cleared Pertac® Universal Bond and to Ivoclar's Compoglass® SCA (K951836). All products have the same intended use and all but one of the same components. To support substantial equivalence to predicate products, the physical and technical characteristics of Hytac® OSB have been compared to those of Pertac® Universal Bond and Ivoclar's Compoglass® SCA. In addition, the sensitization test has been performed on the final Hytac® OSB product to confirm safe use of the product, and test results show no sensitization.

Hytac® Aplitip® and Hytac® OSB meet the requirements of relevant DIN and ISO standards for dental composite material.

ESPE's 510(k) has been submitted on June 17, 1996, by  
Dr. Barbara Wagner at Am Griesberg 2, D-82229 Seefeld, Germany  
(011-49-8152-700395).